Remarks:

The Applicant would like to thank the Examiner for carefully reviewing the specification and claims and argument presented in a previous response to Office Action. Please reconsider the application in view of the foregoing amendments and the following remarks.

1. Telephone Interview

The Applicant would like to thank the Examiner for courtesies extended in a telephone interview on Feb. 16, 2007. It is the Applicant's understanding that amendment of claim 1 to recite that the acts of inducing a static and radio frequency magnetic field are performed to excite nuclear magnetic resonance phenomena in the entire body substantially simultaneously, and that the fields are arranged to minimize spatial variation in nuclear magnetization in the body would make claim 1 allowable over the prior art presently of record in the application.

Agreement was not reached with respect to claims 12, 23 and 33, and the Applicant is required to submit argument in response to rejections set forth in the Office Action of January 29, 2007. Such argument is presented in these Remarks.

2. Status of the Claims

Claims 1-43 are pending in the application. Claims 1, 12, 23 and 33 are independent. Claims 1 and 6-11 stand rejected as obvious over Van Yperen (U.S. Pat. No. 5,402,787) in view of Patrick et al. (U.S. Pat. No. 4,720,679 – "Patrick"). Claims 12, 17-23, 27-29, 33, 37-39 and 43 stand rejected as obvious over Van Yperen in view of Patrick in further view of Dale et al. (U.S. Pat. No. 7,078,899 – "Dale"). Claims 2 and 14 stand rejected as obvious over Van Yperen in view of Patrick in further view of Tomlinson et al. (U.S. Pat. No. 4,034,191). Claims 15, 16, 31, 32, 41 and 42 stand rejected as obvious over Van Yperen in view of Patrick in further view of Dale and Bottomley. Claims 13, 24-26, 34-36 and 40 stand rejected as obvious over Van Yperen in view of Patrick in further view of Dale and Kimmlingen et al. (U.S. Pat. No. 6,717,409 – "Kimmlingen").

3. Claim rejections - 35 U.S.C. § 103(a)

a. Claim 1

Independent claim 1 stands rejected as obvious over Van Yperen in view of Patrick. To the extent the rejection may apply to claim 1 as amended, the Applicant respectfully traverses the rejection for the following reasons.

As the Applicant has already stated in a Reply to the previous Office Action, Claim 1 recites a method for measuring whole body composition. The method of claim 1 includes inducing static and radio frequency magnetic fields in a volume. The body is disposed within the volume. NMR signals are detected from within the body. In the invention of claim 1, the static and radio frequency magnetic fields are arranged such that NMR phenomena are excited in the entire body substantially simultaneously. The static and RF magnetic are arranged to minimize spatial variation in nuclear magnetization. NMR signals related to the NMR phenomena are detected. The composition of the whole body is determined from the detected NMR signals.

In the Applicant's invention, the static and radio frequency magnetic fields are arranged in a manner such that spatial variation of nuclear magnetization is minimized. The resulting NMR signals are substantially independent of the body position within the volume. In this way and important result of the claimed invention, namely that the NMR signals from any part of the body are substantially independent of the position within the volume can be achieved. The Applicant has disclosed in the Specification arrangements of magnet, antenna and particular attributes of the RF pulses applied to the antenna that are capable of inducing the claimed magnetization and NMR phenomena inducement. The Applicant has determined that it is possible to obtain precise, quantitative NMR analysis of the composition of a body which may move (change position during or between measurements) within the examination volume.

Van Yperen shows a conventional NMR imaging system. All NMR imaging systems such as the one shown in Van Yperen include a magnet for inducing a static magnetic field, and antennas for inducing radio frequency magnetic fields in a patient disposed in an examination volume. However, NMR imaging systems also include gradient magnetic field inducing devices for superimposing gradient magnetic fields on the static magnetic field. The gradient fields are

generally arranged in three orthogonal directions such that each point in space within the examination volume is associated with a unique amplitude of static magnetic field. Each point in space is thus associated with a unique NMR frequency. Thus, the NMR signal from every point in space is uniquely associated with a particular NMR frequency. The NMR signal amplitude from each point in space is mapped to an imaging device, such as photographic or video gray scale, to generate images of the interior of the patient. In NMR imaging devices in general, and the ones shown in Van Yperen and in Patrick are no exceptions, NMR phenomena are not induced in the entire body substantially simultaneously, but are induced essentially point by point, or pixel by pixel. To image the entire body, NMR phenomena must be induced in each point in space individually by applying RF pulses to the antenna at individual frequencies to induce NMR phenomena at corresponding points in space in the body where the RF magnetic field frequency is at the Larmor frequency for the static magnetic field amplitude associated with each image point. The individual NMR signals from each pixel are then integrated to form an image. Thus, one affirmative limitation of claim 1, namely that the static and RF fields are arranged to induce NMR phenomena in the entire body substantially simultaneously, is clearly not shown in any of the art of record.

Another limitation of claim 1, that the static and magnetic fields are arranged to minimize spatial variation of nuclear magnetization in the body, is not shown in any of the art of record. The Applicant has disclosed antenna structures and RF pulse characteristics that are intended to minimize such spatial variation. The description of the foregoing is in the Applicant's specification in paragraphs 0057 to 0066. In imaging devices, such as those disclosed in the prior art of record, the spatial variation in nuclear magnetization is not minimized by any particular device or RF pulse properties such as disclosed by the Applicant. To properly image using static and gradient magnetic fields, it is only necessary to know the spatial distribution of static magnetic field amplitude so that NMR signals can be properly induced and then attributed to their position of origin within the body. There is nothing in the art of record that describes minimizing spatial variation in the nuclear magnetization.

Finally, as a result of the Applicant's claimed minimization of spatial variation in nuclear magnetization, the NMR signal is substantially independent of the position of the body within the chamber. In an imaging device, the NMR signal from each part of the body is most definitely not independent of the position of the body part within the volume, of for no other reason than the static magnetic field has gradient fields superimposed thereon.. Any movement of the body within the volume will result in distortion of or even total loss of the NMR signal. In NMR imaging devices such as shown in Patrick and in Van Yperen, the static and RF magnetic fields are such that the NMR signal is completely dependent on the position with in the volume, rather than independent as required by claim 1.

Patrick shows a conventional NMR imaging system as well. The cited portion of Patrick, "whole body separation of lipids and water", starting at col. 6, line 66 is merely an expression of the result obtained using the system shown in Patrick. The Applicant believes the Examiner has seized on the phrase "whole body separation" as evidence that Patrick discloses the missing elements of claim 1 not found in Van Yperen, however, Patrick discloses no such thing. As the Applicant has well explained in the previous Reply, it is entirely possible to generate an image over an entire body using prior art NMR imaging devices. Prior art devices do not, however disclose composition analysis of the entire body in the manner of claim 1.

The apparatus disclosed in Patrick conventionally divides a body to be imaged into subvolumes called "pixels" (as described in Patrick). The improvement purported by Patrick over prior art NMR imaging is processing the NMR spin echoes such that the image obtained from each pixel so that the pixel signal is separated into a water component and a lipid component. Such separation reduces blurring of the images caused by lipids from the final image. Notwithstanding the statement in Patrick that "whole body separation" of lipids and water are possible, Patrick absolutely does not show the static and radio frequency magnetic fields are arranged such that the NMR signals from any part of the body are substantially independent of the position of the body within the volume as recited in claim 1.

Furthermore, Patrick generates a final image by assembling the pixels into a whole image. The Applicant respectfully refers the Examiner to the following portion of Patrick, which states:

> In an improved two scan method, the magnitude is taken before the addition and subtraction. Recall that in general, each scan produces a real image and an imaginary image. When the magnitude is taken before the addition and subtraction, a water versus lipid image is not created. Rather, the water is separated from the lipid on a pixel by pixel basis. The resultant image which results from this addition contains the contribution in each pixel of either the water or the lipid which ever has the greatest signal strength. The subtraction image contains the one with the smaller signal strength. This technique is advantageous in that it is immune from static magnetic field inhomogeneities. Although separate water vs. lipid images are not generated, the pixel-by-pixel separation is sufficient for many purposes such as computed T2 relaxation times, some aspects of image resolution restoration from the chemical shift artifacts, and the like.

See Patrick, col. 10, lines 16-34. Note the underlined portion of Patrick which states that an image is generated, pixel by pixel, and the image value assigned to each pixel is either water or lipid, depending on which signal element in the particular pixel has the greater amplitude. Thus, Patrick discloses what is in essence the same underlying technique as in Van Yperen, namely pixel by pixel imaging. Patrick does not disclose whole volume quantitative compositional analysis by inducing NMR phenomena in the whole body substantially simultaneously.

Also as stated in response to the prior Office Action, "determining composition" as used in the Applicant's claims is clearly intended to mean quantitatively determining amounts of one or more constituent substances present within the body portion being analyzed. Numerous references in the Applicant's specification concerning the analysis performed using the NMR measurements make this definition quite clear. Prior art NMR imaging techniques, including the one shown in Van Yperen and Patrick do not include quantitative determination of constituent substances from within the particular investigated volume. In NMR imaging techniques known in the art, a body being examined is segmented into relatively small image volumes, called "voxels", (or "pixels" as that term is used in Patrick, that are individually investigated, and for each of which a signal amplitude value is assigned. The signal amplitude value may be derived

from various attributes of spin echo amplitudes in a spin echo measurement sequence (such as CPMG) measured for each voxel (or pixel). Nonetheless, each voxel has associated with it only one final measurement value, and as explained above, such values may be used to generate an image. In generating a complete image of all or a portion of the body being analyzed, the discrete voxel values are applied in some form of display, usually a gray scale visual image representation. Composition of the entire body or part thereof may be inferred by summing the numbers of individual voxels for which the amplitude is a certain value or certain values. For example, bone tissue may be inferred when the signal amplitude is a preselected fraction of maximum possible signal amplitude in each voxel. The number of voxels over the entire body image represented by bone signal amplitude is then determined, and a fractional volume of bone tissue in the entire body may be determined by dividing the number of bone-containing voxels by the total number of voxels in the imaged body. Neither Van Yperen nor Patrick discloses, with respect to imaging, anything other than what is described above.

The foregoing explanation of prior art image analysis is well described in the Applicant's Background of the Invention portion of the present application.

The Applicant's claimed invention is quite different in that whole body composition is determined from the detected nuclear magnetic resonance signals in the entire body. In the Applicant's claimed invention, the whole body itself constitutes an individual voxel in an image. The composition is determined quantitatively from the signals measured entirely within the individual voxel. Such determination of composition is simply not disclosed in any of the prior art made of record, and the Examiner has not cited any specific portion of any of the art that makes such statement.

The Applicant has outlined numerous possible advantages of using the claimed measurement technique, including that by measuring NMR signals over a sufficiently large volume, it is possible to have substantial signal to noise ratio using relatively low static magnetic field strength. As importantly, by analyzing whole body composition in one image voxel, a body composition analysis may be performed in much shorter time than by conventional image

integration. Additionally, because the composition is determined only from the NMR signals in whole body, it is not necessary to determine the body volume to determine fractional constituent amounts, as with prior art imaging techniques. Further, certain attributes of the NMR signals acquired and processed according to the invention may be used to directly determine mass of one or more constituents of the whole body. Such is not possible with prior art imaging techniques, which can only provide information about volume fraction of constituents inferred from image amplitudes in each pixel. Again, the Examiner has made no citation to any of the art of record that suggests any of the foregoing.

To summarize, the prior art of record does not show determining whole body composition using NMR signals from the whole body. Two affirmative limitations of claim 1 are not shown in either or both of Van Yperen and Patrick. Accordingly, claim 1 cannot be made obvious over Van Yperen in view of Patrick.

Claims 2-11 ultimately depend from claim 1 and are believed to be patentable for at least the same reasons advanced with respect to claim 1.

b. Claim 12

Claim 12 also recites assessing whole body composition using NMR signals induced within the entire body. Claim 12 includes that spatial distribution of the static and radio frequency magnetic fields are selected to minimize an objective function. The objective function is related to degree of precision required of the measurement and at least one parameter related to cost of implementing the method, for example, size of the magnet. The Applicant has determined, as explained above with respect to claim1, that it is feasible to assess whole body composition by inducing substantially homogeneous static and RF magnetic fields in the entire body, and assessing composition of the entire body from those signals. Such method elements are clearly not shown in Van Yperen or Patrick. Further, there is nothing in VanYperen or Patrick related to selecting parameters of cost to implement and required degree of measurement precision to minimize and objective function. Accordingly, claim 12 cannot be obvious over Van Yperen in

view of Patrick alone. A possible benefit of the method of claim 12 is to minimize the cost of the apparatus needed to make the measurements with a selected degree of precision.

Dale does not provide the missing elements of claim 12 not disclosed in Van Yperen and Patrick. The Applicant respectfully points out that claim 12 does not recite minimizing the objective function to optimize acquisition parameters. Claim12 requires that the objective function be minimized with respect to precision of measurement and at least one parameter is related to the cost of the apparatus. The Applicant also points out that Dale does not disclose selecting spatial distribution of static and magnetic fields to minimize the objective function.

Dale discloses minimizing an objective function related to acquisition parameters for a conventional imaging measurement. The embodiments disclosed in Dale include one or more of the following features. The objective measures may include image acquisition time/speed, aliasing energy, off-resonance blurring, flow-sensitivity, contrast-to-noise ratio (CNR), perceptual difference, point-spread function main-lobe width, engineering costs, quantitative imaging precision, and other objective image-quality measures and process-quality measures. The optimization constraints may include gradient stimulation and specific absorption rate (SAR) limits and hardware constraints (such as maximum slew-rate and gradient amplitude). Optimized parameters may include repetition time (TR); echo time (TE); number of interleaves, views, or repetitions; flip angle; coil diameter; whether fat suppression or flow compensation is performed; type of coil used (e.g., saddle coil, opposed solenoid, etc.); and other parameters suitable to describe a quality attribute of an image. The exemplary genetic algorithm may be designed to find a set of center-out trajectories (in k-space) that are Pareto-optimal with respect to at least one objective measure relevant to the application of interest.

As stated above, nowhere does Dale disclose minimizing an objective function having as an input both a degree of precision of measurement and a parameter related the cost of the apparatus (such as the size of the magnet). To the extent Dale is relied upon based on disclosures of such elements individually, the Applicant respectfully points out that a beneficial result of the Applicant's claimed invention is an apparatus that can determine composition of a whole body

using NMR signals induced in the body essentially all at once. Because the Applicant's claimed apparatus has such features, it is possible to design an apparatus wherein the claimed objective function is minimized. Because prior art imaging apparatus do not generate NMR signals substantially simultaneously in the whole body, there is no motivation for a person of skill in the art to produce a method according to claim 12. The prior art and the invention of claim 12 deal with fundamentally different procedures.

Accordingly, Dale cannot make the combination of claim 12 obvious because Dale does not disclose the elements of claim 12 not disclosed in Van Yperen and Patrick and because all the art of record deals with imaging rather than whole body composition analysis, there is no reason to combine the disclosures of the prior at to obtain the invention of claim 12.

Claims 13-22 ultimately depend from claim 12 and are believed to be patentable for at least the same reasons advanced with respect to claim 12.

c. Claim 23

Claim 23 as amended recites a nuclear magnetic resonance apparatus configured to perform the method substantially as recited in claim 1. In particular, claim 23 includes a means for analyzing composition of a body from NMR signals induced in the entire body substantially simultaneously and detected from within the body. Analyzing composition, as that term is used in the Applicant's invention, is not disclosed in Van Yperen or Patrick. Further, neither Van Yperen nor Patrick discloses a magnet configured to provide a minimum static magnetic field amplitude (strength) with respect to a required degree of precision of measurement. The magnet disclosed in Van Yperen and in Patrick is a conventional one as used with NMR imaging. The static field amplitude is not minimized in such magnets, but rather is selected to provide sufficient spatial resolution when combined with the gradient fields to identify signals from individual image voxels. Accordingly, claim 23 cannot be obvious over Van Yperen in view of Patrick.

Contrary to what was asserted in the Office Action, Dale does not disclose using a magnet having a minimized static magnetic field amplitude with respect to a required degrees of precision. All of the parameters that Dale can optimize are recited in the paragraph above cited with reference to claim 12, and it is clear from reviewing that paragraph that the static field amplitude is not even mentioned, let alone minimized with respect to degree of precision. Furthermore, Dale deals with imaging devices and not compositional analysis devices. In addition to not disclosing the missing elements of claim 23, Dale does not relate to the same technical problem solved by the Applicant's invention. Accordingly, there is no basis or motivation to combine Dale with the other art of record.

Finally, claim 23 recites that the static and magnetic fields are arranged to induce NMR signals in the entire body substantially simultaneously. The Applicant believes that such feature is not shown in any of the art of record. As a result, combining any of the art of record does not include all the limitations of claim 23.

Claims 24-32 ultimately depend from claim 23 and are believed to be patentable for at least the same reasons advanced with respect to claim 23.

d. Claim 33

Claim 33 recites a nuclear magnetic resonance apparatus for body composition analysis in which the magnet and antenna are arranged to induce substantially uniform magnetization within an examination volume. Van Yperen and Patrick, as previously explained, disclose a conventional NMR imaging device in which the magnet and antenna have no such limitations. Further, claim 33 recites that a size of the examination volume is maximized with respect to the size of the magnet and antenna for a selected degree of precision of measurement. No such limitations are disclosed in Van Yperen or Patrick. Accordingly, claim 33 cannot be obvious over Van Yperen in view of Patrick. Dale, as explained above with reference to claims 12 and 23, does not disclose any manner of increasing uniformity or homogeneity of a static magnetic field and antenna sensitivity distribution to maximize the examined volume with respect to a required

sensitivity of measurement. Therefore, all of the elements of claim 33 are not disclosed in the combination of Van Yperen, Patrick and Dale.

Claims 34-43 ultimately depend from claim 33 and are believed to be patentable for at least the same reasons advanced with respect to claim 33.

This Reply is believed to be fully responsive to each and every ground of rejection cited in the Office Action of January 5, 2007, and the Applicant respectfully requests early favorable action on this application.

Respectfully submitted,

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Richard A. Fagin, Reg. No. 39,182
P.O. Box 1247
Richmond, TX 77406-1247

Telephone: (713) 539-5006
Facsimile: (832) 595-0133